IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Reddy, Manne S. et al.)	Confirm. No.:	6006
Serial No.:	10/809,192)	Art Unit:	1624
Filed:	March 25, 2004)	Examiner:	Moore, Susanna
For:	CRYSTALLINE CETIRIZINE MONOHYDROCHLORIDE		

Docket No.: BULK 3.3-045

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF **NARASIMHA MURTHY HARIKEERTHI** UNDER 37 C.F.R. SECTION 1.132

I, **Narasimha Mmurthy Harikeerthi**, declare:

1. This declaration is submitted pursuant to a response to an Office Action dated April 2, 2007 in the above-referenced patent application.

2. I am employed at Dr. Reddy's Laboratories, Ltd.

3. My position is **Assistant Manager** in **Research and Development** department.

4. I am an experienced pharmaceutical chemist. I am graduated from **Jawaharlal Nehru Technological University (JNTU)** with **M. Sc., (Applied Chemistry)**, degree in the year 2005. I have **13 years** of experience in pharmaceutical industry, with **10 years** of specific experience in pharmaceutical solids.

5. It is my understanding that the above-mentioned Office Action alleges that solid material produced in Example IV.1.2 of U.S. Patent No. 6,255,487 to Duchene et al. is the same as the crystalline forms I and II of cetirizine monohydrochloride claimed in Dr. Reddy's U.S. Patent Application No. 10/809,192.

6. For the reasons stated herein below, it is my opinion as one skilled in the art of pharmaceutical chemistry and bulk actives that the above-mentioned solid disclosed in Duchene

cannot be identical to any crystalline cetirizine monohydrochloride claimed in Dr. Reddy's U.S. Patent Application No. 10/809,192.

7. Duchene specifically identifies the material produced in Example IV.1.2. as cetirizine free base. See col. 19, lines 45-46.

8. In my view as one skilled in the art, there is no room for significant doubt that the material of Example IV.1.2 of Duchene is in fact cetirizine free base.

9. Thus, the first portion of hydrochloric acid (0.05M, which is 8 ml of aqueous 6N HCl) is clearly used to neutralize the potassium component of the reacted 0.05 moles of potassium salt of 2-(1-piperazinyl) ethoxyacetate, which is a base and is present in the reaction from the beginning. The pH of the solution is not indicative of salt formation and the resulting oil cannot be a salt either. There is no likelihood whatsoever for formation of cetirizine hydrochloride at that stage.

10. The second portion of the hydrochloric acid (lines 38-9) is added to neutralize unreacted 2-(1-piperazinyl) ethoxyacetate. Importantly, the addition is accomplished in an organic solvent, acetone, and thus clearly signifies its purification/isolation purpose, rather than a salt preparation carried out in water where it is possible to lower pH to a degree significant enough to form a salt.

11. In contrast, Dr. Reddy's process for making a hydrochloride salt of cetirizine is carried out to a definitive pH (2-3), in water. See Specification, at p. 19, Example 1.

I verify under penalty of perjury that the forgoing is my true opinion.

HKN Murthy

Narasimha Murthy Harikeerthi

Date:28 September, 2007